

## REMARKS

The Office Action dated September 15, 2003, has been received and reviewed. Claims 1-6 are pending in this application. Claims 1-2 have been withdrawn from consideration. Claims 3-6 stand rejection. Applicants respectfully request reconsideration of the application as amended herein and in view of the remarks below.

### I. Claim Amendments

Applicants have cancelled Claims 1-2 without prejudice or disclaimer, thus affirming their election of the present claims. Applicants have amended Claims 3 and 6 to clarify the language in these claims. It is respectfully submitted that the claims as amended are stated in a manner that is not narrower than the original claims.

### II. Double Patenting

Claims 3-6 are rejected under the judicially created doctrine of double patent over Claims 19 to 29 and 32-34 of U.S. Patent 6,369,087. Applicants note that with respect to the double patenting rejections based on 35 U.S.C. § 101, M.P.E.P. § 804 provides:

A reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent [or related pending patent application]. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there were such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.

Here, Applicants respectfully submit that independent claim 3, of which claims 4-6 subsequently depend from in view of Claims 19 to 29 and 32-34 of U.S. Patent 6,369,087, recites embodiments of the invention that fall within the scope of present independent claim 3, but not the other claims. Claims 19 to 29 and 32-34 of the '087 patent recites a "solid state composition, wherein each of the 5- and 6-methoxy isomers comprises the same or different diastereomers selected from the group consisting of: (a)  $S_{xa}-R_{4q}$ ; (b)  $S_{xa}-R_{4z}$ ; (c)  $S_{xb}-R_{4q}$ ; and (d)  $S_{xb}-R_{4z}$ ; or one or more pharmaceutically acceptable salts, hydrates, or combinations thereof" as well as a "composition comprising

a plurality of complexes present in a solid state, wherein each complex comprises at least two same or different molecules, at a ratio of 1 to 1 of one molecule of a compound".

Distinct from the language of the claims of the '087 patent, Claim 3 of the present application, of which claims 4-6 subsequently depend, recites "A pharmaceutical formulation comprising an omeprazole composition fixed with a ratio of 5-methoxy and 6-methoxy isomers, wherein said ratio is determined by Fourier Transform Raman Spectroscopy." The cited patents do not recite that the pharmaceutical formulation is fixed and determined by Fourier Transform Raman Spectroscopy. Independent Claim 3 of the present application does not recite diastereomers, metal cations, or one to one ratios. Therefore, independent Claim 3, and Claims 4-6 of the present application which depend from Claim 3, are not the "same invention" as that defined by Claims 19 to 29 and 32-34 of U.S. Patent 6,369,087.

Accordingly, Applicants respectfully request that the 35 U.S.C. § 101 rejection be withdrawn.

### **III. Claims Rejections – 35 U.S.C. § 112, second paragraph**

Claims 3-6 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action questions the use of the term "fixed ratio". The test for definiteness under 35 U.S.C. § 112, second paragraph is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986). Applicants note that the application discusses the term "fixed ratio" throughout, but have amended Claim 3 to further recite wherein said ratio is determined by Fourier Transform Raman Spectroscopy. Applicants submit that this new language clarifies the term fixed. Furthermore, Applicants have amended Claim 6 to depend from Claim 3 and to recite "wherein a predetermined ratio of 5-methoxy and 6-methoxy omeprazole is selected to produce the pharmaceutical formulation." Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejection to Claims 3-6.

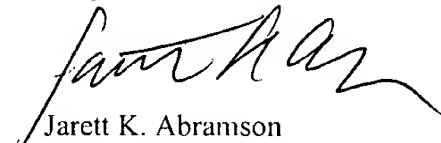
In re: Whittle et al.  
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### CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully submitted,

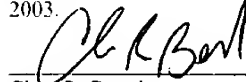


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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 17, 2003.



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